

II. AMENDMENTS TO THE CLAIMS

This Listing Claims shall replace all prior versions, and listings, of the claims in the application.

Listing of Claims

Claim 1 (previously presented): A transdermal delivery device comprising:

a drug containing layer comprising an analgesically effective amount of an opioid agonist and a plurality of microspheres dispersed in the drug containing layer,
the microspheres comprising a microemulsion of an opioid antagonist and being visually indiscernible in the drug containing layer,

wherein the opioid antagonist is not releasable from the transdermal delivery device applied topically intact to a skin of a human patient, and is releasable from the transdermal delivery device administered intraorally.

Claim 2 (previously presented): The transdermal delivery device of claim 1, wherein the microspheres have a mean diameter of from about 1 to about 500 microns.

Claim 3 (previously presented): A transdermal delivery device comprising:

a drug containing layer comprising an analgesically effective amount of an opioid agonist and a plurality of microspheres dispersed in the drug containing layer,
the microspheres having a mean diameter of from about 1 to about 500 microns and comprising (i) an opioid antagonist, (ii) a polyester copolymer of lactic and glycolic acid and (iii) calcium chloride,

wherein the opioid antagonist is not releasable from the transdermal delivery device applied topically intact to a skin of a human patient, and is releasable from the transdermal delivery device which is administered intraorally, chewed, soaked, punctured, or torn.

Claim 4 (previously presented): The transdermal delivery device of claim 3, wherein the microspheres have the mean diameter of from about 1 to about 300 microns.

Claim 5 (previously presented): The transdermal delivery device of claim 1, wherein the microspheres are multiphasic polymeric microspheres in which the opioid antagonist is dispersed in oily droplets in a polymeric matrix of a polymer selected from the group consisting of polyesters, polyethers, poly(orthoesters), polysaccharides, cyclodextrins, chitosans, poly(e-caprolactones), polyanhydrides, albumin, blends, copolymers thereof and mixtures thereof.

Claim 6 (previously presented): The transdermal delivery device of claim 1, wherein the microspheres further comprise a polymer selected from the group consisting of polyesters, polyethers, poly(orthoesters), polysaccharides, cyclodextrins, chitosans, poly(e-caprolactones), polyanhydrides, albumin, blends, copolymers thereof and mixtures thereof.

Claim 7 (previously presented): The transdermal delivery device of claim 1, wherein the microspheres consist essentially of the microemulsion of the opioid antagonist and a polymer selected from the group consisting of polyesters, polyethers, poly(orthoesters), polysaccharides, cyclodextrins, chitosans, poly(e-caprolactones), polyanhydrides, albumin, blends, copolymers and mixtures thereof.

Claim 8 (previously presented): The transdermal delivery device of claim 1, wherein the microspheres consist essentially of the microemulsion of the opioid antagonist dispersed in a polymeric matrix.

Claim 9 (previously presented): The transdermal delivery device of claim 1, wherein the microspheres have a mean diameter of from about 300 to about 500 microns.

Claim 10 (previously presented): The transdermal delivery device of claim 1, wherein the microspheres have a mean diameter of from about 200 to about 500 microns.

Claim 11 (previously presented): The transdermal delivery device of claim 1, wherein the microspheres have a mean diameter of from about 125 to about 200 microns.

Claim 12 (previously presented): The transdermal delivery device of claim 1, wherein the opioid antagonist is releasable if the transdermal delivery device is chewed, soaked, punctured, or torn.

Claim 13 (previously presented): The transdermal delivery device of claim 12, wherein the effect of the opioid agonist is at least partially blocked by the opioid antagonist when the integrity of the microspheres is disrupted, and the disrupted microspheres are administered intraorally, orally, intranasally, parenterally or sublingually.

Claims 14-17 (cancelled)

Claim 18 (previously presented): The transdermal delivery device of claim 1, wherein the opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof.

Claim 19 (previously presented): The transdermal delivery device of claim 1, wherein the microspheres have a mean diameter of from about 50 to about 100 microns.

Claim 20 (cancelled)

Claim 21 (previously presented): The transdermal delivery device of claim 1, wherein the drug containing layer is a matrix layer.

Claim 22 (previously presented): The transdermal delivery device of claim 21, wherein the matrix comprises a material selected from the group consisting of polyethylene, polypropylene, ethylene/propylene copolymers, ethylene/ethylacrylate copolymers, ethylenevinyl acetate copolymers, rubber, synthetic homo-, co- or block polymers of rubber, polyacrylic esters and the copolymers thereof, polyurethanes, polyisobutylene, chlorinated polyethylene, polyvinylchloride, vinyl chloride-vinyl acetate copolymer,

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polymethacrylate polymer (hydrogel), polyvinylidene chloride, poly(ethylene terephthalate), ethylene-vinyl alcohol copolymer, ethylene vinyloxyethanol copolymer, silicone copolymers, cellulose polymers, polycarbonates, polytetrafluoroethylene and mixtures thereof.

Claim 23 (previously presented): The transdermal delivery device of claim 21, wherein the matrix comprises a polymer selected from the group consisting of silicone copolymers, silicone polymers that are cross-linkable, copolymers having dimethyl and/or dimethylvinyl siloxane units which can be crosslinked, block copolymers based on styrene and 1,3-dienes, polyisobutylenes, and polymers based on acrylate and/or methacrylate.

Claims 24-30 (cancelled)

Claim 31 (previously presented): The transdermal delivery device of claim 1, wherein the microspheres have a mean diameter of from about 1 to about 200 microns.

Claim 32 (previously presented): The transdermal delivery device of claim 1, wherein the microspheres have a mean diameter of from about 1 to about 100 microns.

Claim 33-36. (Cancelled)

Claim 37 (previously presented): The transdermal delivery device of claim 3, wherein the opioid antagonist is in the form of an emulsion.

Claim 38 (previously presented): The transdermal delivery device of claim 3, wherein the polyester copolymer of lactic and glycolic acid is poly(lactic-co-glycolic acid).

Claim 39 (previously presented): A transdermal delivery device comprising:
a drug containing layer comprising an analgesically effective amount of an opioid agonist and a plurality of microspheres dispersed in the drug containing layer,

the microspheres having a mean diameter of from about 1 to about 500 microns and comprising (i) an opioid antagonist and (ii) a copolymer of poly(e)caprolactone or a poly(orthoester),

wherein the opioid antagonist is not releasable from the transdermal delivery device applied topically intact to a skin of a human patient, and is releasable from the transdermal delivery device which is administered intraorally, chewed, soaked, punctured, or torn.

Claim 40 (previously presented): The transdermal delivery device of claim 39, wherein the microspheres comprise (i) an opioid antagonist and (ii) a copolymer of poly(e)caprolactone.